REMARKS

This Amendment is submitted with a Request for Continued Examination, and constitutes the required submission for the Request for Continued Examination. This Amendment is responsive to the final Office Action dated May 13, 2008. Applicant has amended claims 1, 3, 5, 11, 12, 14, and 15, and added claims 21 and 22. Claims 1–22 are pending.

Claim Rejection Under 35 U.S.C. § 112, Second Paragraph

In the final Office Action, claims 1–10 and 12–20 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action stated that, "[i]t is unclear and indefinite how the invention detects a need for an added safety factor in response to a perceived increase in the pacing threshold if there is an absence of a pacing threshold test. The Examiner considers that since the invention monitors for indications of an increase in the pacing threshold, a testing indicating an increase in threshold (i.e., a threshold test) is necessarily performed."[1]

Applicant has amended claims independent claims 1 and 12 for purposes of clarification. In particular, claims 1 and 12 as amended clarify that a pacing threshold search comprises delivering pacing pulses. Thus, claim 1 as amended is clear that a method includes monitoring for indicators of a likely increase in pacing threshold in the absence of a pacing threshold search that comprises delivering pacing pulse, and claim 12 as amended is clear that an implantable medical device includes means for monitoring for indicators of a likely increase in pacing threshold in the absence of a pacing threshold search that comprises delivering pacing pulses.

Applicant submits that independent claims 1 and 12 as amended, as well as claims 2–10 and 13–20, which depend from claims 1 or 12, particularly point out and distinctly claim the subject matter, as required by 35 U.S.C. § 112, second paragraph. Reconsideration and withdrawal the rejection of the claims under 35 U.S.C. § 112, second paragraph is respectfully requested.

[1] Office Action at p. 2, item 4.

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Claim Rejection Under 35 U.S.C. §§ 102(b) and 103(a)

In the final Office Action, independent claim 11 was rejected under 35 U.S.C. § 102(b) was rejected as being anticipated by Sloman et al. (European Patent No. 1 136 098 A2, hereinafter "Sloman"), as well as being anticipated by Schloss (U.S. Patent No. 6,456,882). Claims 1, 6–10, 12, and 16–20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sloman. In addition, claims 2–5 and 13–15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sloman in view of Schloss. Claims 1–5 and 12–15 were also rejected under 35 U.S.C. § 103(a) as being unpatentable over Schloss and claims 6–10 and 16–20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Schloss (in view of Sloman et al.). Applicant respectfully traverses the rejection of the claims to the extent such rejection may be considered applicable to the amended claims.

Independent Claims 1, 11, and 12

Independent claim 1 as amended clarifies that a method of providing capture management comprises monitoring for indicators of a likely increase in pacing threshold in the absence of a pacing threshold search that comprises delivering pacing pulses, and increasing a safety factor used in setting a pacing pulse output energy if an indicator of increased pacing threshold is detected.

Independent claim 11 is directed to an implantable medical device (IMD) includes a microprocessor that control a pulse generator, receives sensed data from at least one electrode, and increases a safety factor used for setting the pacing pulse energy delivered by the pulse generator when an indicator of increased pacing threshold is detected. According to claim 11 as amended, the sensed data includes an indicator of increased pacing threshold and the sensed data is generated in the absence of a pacing threshold search that comprises delivery of the pacing pulses.

Independent claim 12 as amended clarifies that an IMD comprises means for monitoring for indicators of a likely increase in pacing threshold in the absence of a pacing threshold search that comprises delivering pacing pulses and means for increasing a safety factor used in setting a pacing pulse output energy if an indicator of increased pacing threshold is detected.

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The cited references fail to disclose each and every element of independent claims 1, 11, and 12. For example, the cited references fail to disclose or suggest monitoring for indicators of a likely increase in pacing threshold in the absence of a pacing threshold test that comprises delivery of stimulation pulses, as required by independent claims 1, 11, and 12.

Sloman

Sloman discloses an implantable stimulation device that performs periodic capture threshold tests to generate a statistical model of threshold data.[2] According to Sloman, the periodic threshold tests require the delivery of pacing pulses.[3] For example, Sloman describes a threshold search algorithm that includes delivering a stimulation pulse and progressively decreasing the stimulation energy until loss of capture, i.e., a failure to depolarize cardiac tissue, is detected.[4] Sloman discloses that the statistical model is used to adjust the stimulation pulse energy level to a level that minimizes the risk of loss of capture.[5] In particular, Sloman states that the safety margin of the stimulation pulse energy level is determined by the variability of the threshold data, i.e., the data that is obtained by delivering stimulation pulses that trigger an evoked response.[6]

The Office Action acknowledged that Sloman does not disclose a method that comprises monitoring for indicators of a likely increase in pacing threshold in the absence of a pacing threshold test.[7] Rather, Sloman requires such a pacing threshold test. However, the Office Action reasoned that Sloman discloses that "it is known in the art to add a safety factor/margin to the pacing pulse in the event that an increase in pacing threshold is perceived," and, accordingly, "it is considered obvious to one of ordinary skill in the art at the time the invention was made to add a safety factor whenever an increase in pacing threshold is sensed."[8] Applicant respectfully disagrees with this conclusion of obviousness.

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[2] Sloman at Abstract.
[3] Sloman at paragraph [0004].
[4] Sloman at paragraph [0064].
[5] Sloman at Abstract.
[6] Sloman at Abstract and *see* claim 1.
[7] Office Action at p. 5, item 9.
[8] Office Action at p. 5, item 9.

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While Sloman describes techniques for adjusting a safety margin of a capture threshold, Sloman requires delivering pacing pulses in order to generate data that is used to increase a safety factor. According to the technique disclosed by Sloman, threshold searches that include the delivery of pacing pulses are required in order to generate a statistical model that is used to adjust the safety margin.[9] In contrast, claim 1 and 12 require monitoring (or means for monitoring) for indicators of a likely increase in pacing threshold in the absence of a pacing threshold search that comprises delivering pacing pulses. The indicators of a likely increase in pacing energy serves as an alternative to performing a pacing threshold test to facilitate increasing the pacing threshold, even in situations where the pacing threshold test may not be successfully performed.[10]

Given the fact that Sloman requires the performance of threshold tests that include the delivery of pacing pulses in order to generate its statistical model, there is no apparent reason why one skilled in the art would have modified Sloman to eliminate the pacing threshold tests in order to monitor for other indicators of a likely increase in pacing threshold. Such a modification would render Sloman inoperable for its intended purpose, which is impermissible.[11] For example, such a modification would eliminate all the threshold data that is used to generate a statistical model, thereby eliminating the very basis by which Sloman modifies a stimulation pulse energy level.

Nothing in Sloman suggests a method or IMD that monitors for indicators of a likely increase in a pacing threshold in the absence of a pacing threshold search that comprises delivering pacing pulses, as recited by Applicant's independent claims 1 and 12. Indeed, Sloman only contemplates techniques for adjusting a stimulation pulse energy based on a statistical model that is generated by performing a threshold test that includes delivering stimulation pulses. For at least these reasons, Sloman fails to render independent claims 1 and 12 obvious.

Independent claim 11 as amended requires a microprocessor that receives sensed data, which includes an indicator of increased pacing threshold, where the sensed data is generated in the absence of a pacing threshold search that comprises delivery of pacing pulses. For similar reasons discussed above with respect to independent claims 1 and 12, Sloman also fails to render independent claim 11 obvious.

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[9] Sloman at col. 3, ll. 17–20 and col. 12, ll. 40–43.
[10] *See, e.g.*, Applicant's disclosure at paragraph [0016].
[11] *See* MPEP 2143.01(V).

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Schloss

Schloss also fails to disclose or suggest each and every element of Applicant's independent claims 1, 11, and 12. For example, Schloss fails to disclose or suggest monitoring for indicators of a likely increase in pacing threshold in the absence of a pacing threshold search that comprises delivering pacing pulses, as required by independent claim 1, or means for monitoring for indicators of a likely increase in pacing threshold in the absence of a pacing threshold search that comprises delivering pacing pulses, as required by independent claim 12.

The Office Action acknowledged that Schloss does not disclose monitoring for indicators of a likely increase in pacing threshold in the absence of a pacing threshold test.[12] According to the Office Action, Schloss discloses that "it is known in the art to add a safety factor/margin to the pacing pulse in the event that an increase in pacing threshold is perceived."[13] On this basis, the Office Action asserted that it would have been obvious to one of ordinary skill in the art at the time the invention was made "to add a safety factor whenever an increase in pacing threshold is sensed."[14] However, this conclusion of obviousness overlooks the fact that Applicant's independent claims require the monitoring for indicators of a likely increase in pacing threshold in the absence of a pacing threshold search. Accordingly, while the Examiner considers it obvious to add a safety factor when an increase in pacing threshold is perceived, neither Schloss nor any other prior art of record contemplates any way to perceive an increase in pacing threshold absent a pacing threshold test. As noted above, Applicant has amended independent claims 1 and 12 to clarify that the pacing threshold search comprises delivering pacing pulses.

Applicant agrees that Schloss discloses a technique for increasing a threshold stimulation energy level. Schloss does not, however, contemplate monitoring for indicators of a likely increase in pacing threshold in the absence of a pacing threshold search that comprises delivering pacing pulses. Instead, Schloss discloses increasing a threshold stimulation energy level based upon the frequency with which cardiac tissue is captured in response to the delivery of stimulation pulses.[15] Thus, Schloss requires the delivery of pacing pulses in order to adjust the threshold stimulation energy level.

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[12] Office Action at p. 6, item 11.
[13] Office Action at p. 6, item 11.
[14] Office Action at p. 5, item 9.
[15] Schloss at col. 3, ll. 10–22.

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Schloss discloses a method that includes determining whether an electrical stimulus applied to the heart is of sufficient energy to depolarize the cardiac tissue, i.e., to evoke a response.[16] Schloss discloses that a loss-of-capture performance value may be determined in response to the absence of an evoked response to a stimulation pulse.[17] The loss-of-capture performance value may be determined by comparing the number of captured cycles to the non-captured cycles.[18] According to Schloss, the safety margin value for the stimulation may be increased if the loss-of-capture performance value exceeds a threshold value.[19] Thus, according to Schloss, a threshold stimulation energy level is increased by a safety margin based on information that is obtained by delivering pacing pulses.

Schloss discloses a capture verification technique in which signals from the patient's heart are monitored after a pacing pulse is delivered in order to determine whether the pulses stimulated the patient's heart.[20] This contradicts the requirements of Applicant's independent claims 1 and 12, which requires monitoring (or means for monitoring) for indicators of a likely increase in pacing threshold are monitored in the absence of a pacing threshold search that includes delivering pacing pulses.

There is no apparent reason why one skilled in the art would have modified Schloss to eliminate the delivery of pacing pulses in order to adjust the threshold safety margin. For example, such a modification would eliminate the delivery of stimulation pulses to the patient's heart, thereby eliminating the need for the implantable cardiac stimulation device and the need for modifying a threshold safety margin. Thus, such a modification would render Schloss inoperable for its intended purpose, which is impermissible.[21]

Independent claim 11 as amended requires sensed data that includes an indicator of increased pacing threshold, where the sensed data is generated in the absence of a pacing threshold search that comprises delivery of pacing pulses. For similar reasons discussed above with respect to independent claims 1 and 12, Schloss also fails to render independent claim 11 obvious.

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[16] Schloss at col. 6, ll. 45–48.
[17] Schloss at col. 12, ll. 3–8.
[18] Schloss at col. 12, ll. 12–17.
[19] Schloss at col. 12, ll. 27–30.
[20] Schloss at col. 2, ll. 6–8.
[21] *See* MPEP 2143.01(V).

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Dependent Claims

Claims 2–10 depend from independent claim 1 and claims 13–20 depend from independent claim 12. Claims 2–10 and 13–20 are patentable over the cited references for at least the reasons provided above with respect to independent claims 1 and 12. In addition, the dependent claims recite additional elements that are neither disclosed nor suggested by the cited art. Applicant addresses some of the dependent claims below for purposes of illustration.

Claim 3 is directed toward a method that includes setting a time interval during which an increased safety factor is maintained, and restoring the safety factor to a programmed value after the time interval has expired, where the duration of the time interval is set according to the type of indicator of increased pacing threshold that has been detected. The Office Action found that claim 3 is unpatentable over Sloman in view of Schloss or obvious in view of Schloss. In particular, the Office Action concluded that claim 3 is obvious because Schloss discloses increasing a safety margin value and then incrementally decreasing the safety margin value in response to a safety margin adjustment criteria not being met for a specified time period.[22] Applicant respectfully disagrees with the Office Action's conclusion of obviousness.

Even if Schloss did disclose increasing a safety margin value and then incrementally decreasing the safety margin value in response to a safety margin adjustment criteria not being met for a specified time period,[23] Schloss only discloses increasing a safety margin value based on the number of cardiac cycles that do not have an evoked response to stimulation pulses.[24] Thus, it is unclear how Schloss discloses selecting a duration of the time period after which the safety margin value is decreased according to the type of indicator of increased pacing threshold that has been detected, as required by Applicant's claim 3. Schloss fails to disclose or suggest that the duration of the time period for resetting an increased safety margin value is based on any particular factor, much less based on a type of indicator of a increased pacing threshold that is detected.

While the Office Action noted that Schloss discloses resetting an increased safety margin value after a time period has elapsed since a safety margin criteria has been met, the Office Action failed to address the requirements of claim 3. Accordingly, the Office Action failed to

[22] Office Action at pp. 5–6, item 10.
[23] Schloss at col. 3, ll. 42–47.
[24] *See* Schloss at col. 3, ll. 30–41.

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meet the burden of demonstrating how Sloman in view of Schloss or Schloss alone renders claim 3 obvious. As provided in 37 C.F.R. 1.104(c)(2), the Examiner must designate the particular part of a reference that is relied upon as nearly as practicable. However, with respect to claim 3, as well as many of the dependent claims, the Examiner has failed to do so. The Office Action did not explain how Schloss or Sloman disclose restoring a safety factor to a programmed value after a time interval has expired, where the duration of the time interval is set according to the type of indicator of increased pacing threshold that has been detected. Thus, on at least the basis that the Office Action failed to meet the burden of demonstrating that Schloss or Sloman in view of Schloss disclose each and every element of claim 3, Applicant respectfully requests clarification of the rejection of claim 3 or withdrawal of the rejection.

Claim 14 is directed toward an IMD that includes a means for setting a time interval during which an increased safety factor is maintained, and means for restoring the safety factor to a programmed value after the time interval has expired, where the duration of the time interval is set according to the type of indicator of increased pacing threshold that has been detected. For at least the reasons discussed with respect to claim 3, Applicant's claim 14 is patentable over Schloss and Sloman in view of Schloss.

Claims 6–10 and 16–20 specify different types of indicators of an increased pacing threshold. In support of the rejection of claims 6–10 and 16–20, the Office Action asserted that Sloman or Schloss in view of Sloman disclose the different types of indicators of an increased pacing threshold recited in claims 6–10 and 16–20. Applicant respectfully disagrees. Sloman or Schloss in view of Sloman fail to disclose or even contemplate any relationship between an likely increase n pacing threshold and the indicators recited in Applicant's 6–10 and 16–20.

Claims 6 and 16 specify that the indicators of an increased pacing threshold include a change in lead impedance. The Office Action asserted that Sloman discloses an impedance measuring circuit 112, and, therefore, renders claims 6 and 16 obvious. This conclusion of obviousness, however, appears to overlook the fact that Sloman fails to disclose any relationship between lead impedance and an increased pacing threshold. Indeed, Sloman or Schloss in view of Sloman fail to contemplate monitoring for a change in lead impedance and increasing a safety factor used in setting a pacing pulse output energy if the change in lead impedance is detected. For example, as described above, Sloman only contemplates adjusting a stimulation pulse energy

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based on a statistical model of threshold data that is generated based on periodic threshold tests that require the delivery of stimulation pulses.

Sloman or Schloss in view of Sloman also fail to disclose or even suggest that arrhythmia detections, a pacing mode switch, a refractory sensed event or an event triggered by a refractory sensed event may be indicators of an increased pacing threshold. Accordingly, neither Sloman nor Schloss in view of Sloman render claims 7–10 or 17–20 obvious. For example, with respect to claims 7 and 17, which specify that indicators of a likely increase in pacing threshold comprises arrhythmia detections, Sloman only contemplates detection of an arrhythmia for controlling the timing of an electrical shock therapy that is aimed at terminating the arrhythmia.[25]

In contrast, Applicant has recognized that an indicator of an increased pacing threshold may be related to the occurrence of an arrhythmia.[26] As Applicant's disclosure provides, the atrial substrate is believed to be more difficult to capture after an episode of atrial fibrillation or atrial flutter.[27] Contrary to the Office Action's assertions, there would have been no apparent reason to modify Sloman to monitor for indicators of a likely increase in pacing threshold, where the indicators comprise an arrhythmia detection, as required by claims 7, 8, 17, and 18. Again, Sloman only contemplates adjusting a stimulation pulse energy based on a statistical model of actual, measured threshold data. Schloss only contemplates adjusting a stimulation energy level based on the frequency of capture.

Sloman and Schloss, alone or in combination with each other, fail to disclose each and every limitation set forth in claims 1–20. For at least these reasons, claims 1–20 are patentable over the cited references. Reconsideration and withdrawal of the rejection of the claims is respectfully requested.

New Claims

Applicant has added claims 21 and 22 to the pending application. The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. As one example, the references fail to disclose or suggest an IMD that includes a

[25] Sloman at col. 11, ll. 44–47.
[26] *See* Applicant's disclosure at paragraph [0046].
[27] *See* Applicant's disclosure at paragraph [0046].

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pulse generator that delivers pacing pulses, at least one electrode in electrical communication with the pulse generator, where the at least one electrode delivers the pacing pulses to cardiac tissue, and a microprocessor that controls the pulse generator, receives sensed data from the at least one electrode, where the sensed data includes an indicator of increased pacing threshold, and increases a safety factor used for setting the pacing pulse energy delivered by the pulse generator when the indicator of increased pacing threshold is detected, as recited by independent claim 22. According to independent claim 22, the indicator is associated with a compromised ability of the microprocessor to perform a pacing threshold search that comprises delivery of the pacing pulses. No new matter has been added by the new claims.

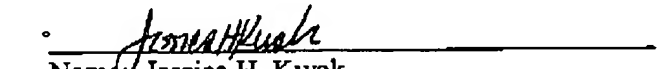
CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

August 13, 2008

By:



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